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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3736	7

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/974,654	MATZINGER ET AL.
	Examiner	Art Unit
	Patricia C. Mallari	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

Claim 73 is objected to because of the following informalities: "suitable" at the end of the claim should be replaced with "suitable site". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 27, 65, and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "said physiological sample" on line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "said vessel characterization element" on line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 65 recites the limitation "said flow characterization" on line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 68 recites the limitation "the step of characterizing the red blood cell character of said site" on lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 7, 12-14, 16, 21, 27, 32-34, 49, 53-55, 58, 59, 65-67, 68, 73, 76, 77, 83, 87-91, 96, and 97 rejected under 35 U.S.C. 102(e) as being anticipated by Yamazaki. Yamazaki discloses an ultrasonic diagnosis apparatus including a paracentetic needle device having a paracentetic needle 100 and adaptor 101 for guiding the needle 100. The apparatus also includes a two-dimensional array probe (ultrasonic probe) 1 on which the adaptor 101 is attached, a system main body 2 to which the probe 1 is attached, and a monitor 3. The body 2 is provided with a unit 12 with a plurality of beamformers 12a-12n and a group of processors, including a Doppler processor 15 for obtaining 3D data with respect to information such as blood flow rate or the like of an object, where flow rate, red blood cell flux, and pulse are related. A processor 16 prepares a 3D image for display on monitor 3, where the information may include the Doppler blood flow information. The insertion and navigation of the needle 100 is then based on the image displayed on monitor 3, thus determining a suitable sampling site based on the flow and sample type characterization (figs. 1-3).

Claims 36, 37, 39, 40, 42, 83, and 86 are rejected under 35 U.S.C. 102(e) as being anticipated by Toida et al. Toida discloses a blood vessel imaging system

comprising a laser 111 emitting light of a wavelength λ, an optical heterodyne optical system 112, first to third photodetectors 113 to 115, a personal computer 122 and an image monitor 123. When taking a blood vessel image, a series of light beams are emitted onto object (subject's finger, for example) 124 and the reflected light is detected by photodetectors 113 to 115. Personal computer 112 creates an image from the output of photodetectors 113 to 115. The image is displayed on monitor 123, and in the image, an artery is displayed as a relatively high density part, while a vein is displayed as a relatively low density part, thereby distinguishing between an artery and a vein. Flow rate V may be determined on the basis of a beat signal detection system output from the optical heterodyne detection system. Also, in any of the disclosed embodiments of Toida, Doppler broadening of the spectrum corresponds to the flow rate of blood in the imaged vessel. Since arterial and venous blood differ in blood flow rates, the artery and vein can also be distinguished using the broadening of the spectrum (figs. 7 & 9).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 12, 13, 16, 27, 32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Barker. Barker teaches a fluid temperature sensing device 10 for use in a system 11 where a cold injectate fluid is delivered from a syringe 12 through a catheter into a patient's blood vessel. A thermistor temperature sensor 14 is disposed

in the distal end of the catheter for sensing the temperature of the blood. Computer 16 determines the flow rate of the blood based on the temperature signal from thermistor 14 (fig. 1).

Claims 1, 3-5, 7, 12, 13, 15-18, 22, 27, 32, 33, 35, 49, 51, 52, 55, 57-59, 65, 69, 73, 75-77, 83, 85, 86, 92, 96, and 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Tiemann et al. Tiemann discloses collimated light in a range of 340 to 700 nm or 700 nm to 100 nm from an intense light source 10 that is focused on a fiber entrance 16 of an optical fiber 14 threaded down the shaft 30 of a hollow needle 20 having a photodiode 24. A computer 36 evaluates the light a test region and backscattered light detected by photodiode 24 to characterize tissue in the test region by determining oxyhemoglobin and deoxyhemoglobin levels (figs 1-3).

Claims 16 and 27- 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. Douglas teaches a lancing device 10 for making an incision through a skin surface S wherein a disposable lancet 12 carries a needle 14 and is displaced into the skin and retracted. Lancet 12 is situated within sleeve 24 of housing 26. After the incision I is made, the housing 26 is pushed repeatedly against the skin to express the appropriate drop of blood or interstitial fluid D from the incision. Capillary tube 14 is used to dispose the sample on test strip 30. Fluid analyzing elements within housing 26 may include a light source 40 and a light detector 42 connected to an electronics unit 44 for monitoring a color change of the sample as the sample reacts with reagents on the strip in order to determine glucose concentration in the sample. In another embodiment, an electrochemical analyzing mechanism is provided in lieu of optical

analyzing elements. The strip 52 would then be provided with a printed circuit and a meter 50 would electrochemically determine the glucose concentration of the sample (figs. 1 and 2)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-10, 61,63, 79, 81, 99, and 101 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Tiemann et al. in view of Douglas et al. Tiemann discloses collimated light in a range of 340 to 700 nm or 700 nm to 100 nm from an intense light source 10 that is focused on a fiber entrance 16 of an optical fiber 14 threaded down the shaft 30 of a hollow needle 20 having a photodiode 24. A computer 36 evaluates the light a test region and backscattered light detected by photodiode 24 to characterize tissue in the test region by determining oxyhemoglobin and deoxyhemoglobin levels (figs 1-3). Tiemann lacks an analyte concentration determination reagent strip.

However, Douglas teaches a lancing device 10 for making an incision through a skin surface S wherein a disposable lancet 12 carries a needle 14 and is displaced into the skin and retracted. Lancet 12 is situated within sleeve 24 of housing 26. After the incision I is made, the housing 26 is pushed repeatedly against the skin to express the appropriate drop of blood or interstitial fluid D from the incision. Capillary tube 14 is

used to dispose the sample on test strip 30. Fluid analyzing elements within housing 26 may include a light source 40 and a light detector 42 connected to an electronics unit 44 for monitoring a color change of the sample as the sample reacts with reagents on the strip in order to determine glucose (or other analyte) concentration in the sample. In another embodiment, an electrochemical analyzing mechanism is provided in lieu of optical analyzing elements. The strip 52 would then be provided with a printed circuit and a meter 50 would electrochemically determine the glucose concentration of the sample, for example (figs. 1 & 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the lancing device of Douglas with the apparatus and method of Tiemann et al. thereby providing analyte concentration information as further information with which a physician may make a more accurate diagnosis.

Claims 11, 23-26, 31, 60, 64, 70-72, 78, 82, 93-95, 98, and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Osemwota. Tiemann discloses collimated light in a range of 340 to 700 nm or 700 nm to 100 nm from an intense light source 10 that is focused on a fiber entrance 16 of an optical fiber 14 threaded down the shaft 30 of a hollow needle 20 having a photodiode 24. A computer 36 evaluates the light a test region and backscattered light detected by photodiode 24 to characterize tissue in the test region by determining oxyhemoglobin and deoxyhemoglobin levels (figs 1-3). Tiemann lacks determining any hemoglobin concentrations. However, Osemwota teaches a four-wavelength pulse oximeter sensor 4 that transmits light across a tissue and detects the absorbance. The absorbance

information is used to determine deoxygenated hemoglobin concentration C2, oxygenated hemoglobin concentration C1, total hemoglobin concentration THb, and a ration of oxygenated to deoxygenated hemoglobin concentration R used to determine oxygen saturation SaO2. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to combine the method and apparatus of Osemwota with that of Tiemann et al. in order to provide more information with which to determine a suitable sampling site.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Scharf. Tiemann discloses collimated light in a range of 340 to 700 nm or 700 nm to 100 nm from an intense light source 10 that is focused on a fiber entrance 16 of an optical fiber 14 threaded down the shaft 30 of a hollow needle 20 having a photodiode 24. A computer 36 evaluates the light a test region and backscattered light detected by photodiode 24 to characterize tissue in the test region by determining oxyhemoglobin and deoxyhemoglobin levels (figs 1-3). Tiemann lacks a second light source. However, Scharf teaches a pulse oximeter 10 having two green light emitters 12 and 14, where the one emitter emits light having a wavelength of 560 nm and the other emits light having a wavelength of 577 nm across a volume of intravascular blood 4. A photodiode 26 detects an optical signal 24 corresponding to the reflectance of the light emitted (fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the pulse oximeter of Scharf with the apparatus and method of Tiemann et al. in order to provide further information to more accurately determine a suitable sampling site.

Claims 40, 41, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Toida et al. Tiemann discloses collimated light in a range of 340 to 700 nm or 700 nm to 100 nm from an intense light source 10 that is focused on a fiber entrance 16 of an optical fiber 14 threaded down the shaft 30 of a hollow needle 20 having a photodiode 24. A computer 36 evaluates the light a test region and backscattered light detected by photodiode 24 to characterize tissue in the test region by determining oxyhemoglobin and deoxyhemoglobin levels (figs 1-3). Tiemann lacks a flow characterization and sample type characterization directed towards the arterial or venous vasculature of the sampling site.

However, Toida discloses a blood vessel imaging system comprising a laser 111 emitting light of a wavelength λ, an optical heterodyne optical system 112, first to third photodetectors 113 to 115, a personal computer 122 and an image monitor 123. When taking a blood vessel image, a series of light beams are emitted onto object (subject's finger, for example) 124 and the reflected light is detected by photodetectors 113 to 115. Personal computer 112 creates an image from the output of photodetectors 113 to 115. The image is displayed on monitor 123, and in the image, an artery is displayed as a relatively high density part, while a vein is displayed as a relatively low density part, thereby distinguishing between an artery and a vein. Flow rate V may be determined on the basis of a beat signal detection system output from the optical heterodyne detection system. Also, Doppler broadening of the spectrum corresponds to the flow rate of blood in the imaged vessel. Since arterial and venous blood differ in blood flow rates, the artery and vein can also be distinguished using the broadening of the

spectrum (figs. 7 & 9). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the blood vessel imaging system of Toida with the method and apparatus of Tiemann et al. in order to provide the user with further information to better determine a suitable sampling site.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Toida et al. as applied to claims 40, 41, 47, and 48 above and further in view of Barker. Tiemann, as modified, lacks a temperature characterization element. However, Barker teaches a fluid temperature sensing device 10 for use in a system 11. A thermistor temperature sensor 14 is disposed in the distal end of the catheter for sensing the temperature of the blood. Computer 16 determines the flow rate of the blood based on the temperature signal from thermistor 14 (fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art to combine the fluid temperature sensing device of Barker with the method and apparatus of Tiemann et al., as modified by Toida et al., in order to provide further information to determine a suitable sampling site more accurately.

Claims 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Toida et al. as applied to claims 40, 41, 47, and 48 above, and further in view of Douglas et al. Tiemann, as modified, lacks an analyte concentration determination reagent test strip. However, Douglas describes a lancing device 10 for making an incision through a skin surface S wherein a disposable lancet 12 carries a needle 14 and is displaced into the skin and retracted. Lancet 12 is situated within sleeve 24 of housing 26. After the incision I is made, the housing 26 is pushed

repeatedly against the skin to express the appropriate drop of blood or interstitial fluid D from the incision. Capillary tube 14 is used to dispose the sample on test strip 30. Fluid analyzing elements within housing 26 may include a light source 40 and a light detector 42 connected to an electronics unit 44 for monitoring a color change of the sample as the sample reacts with reagents on the strip in order to determine glucose (or other analyte) concentration in the sample. In another embodiment, an electrochemical analyzing mechanism is provided in lieu of optical analyzing elements. The strip 52 would then be provided with a printed circuit and a meter 50 would electrochemically determine the glucose concentration of the sample, for example (figs. 1 & 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the lancing device of Douglas with the apparatus and method of Tiemann et al. thereby providing analyte concentration information as further information with which a physician may make a more accurate diagnosis.

Claims 50, 74, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Barker. Tiemann discloses collimated light in a range of 340 to 700 nm or 700 nm to 100 nm from an intense light source 10 that is focused on a fiber entrance 16 of an optical fiber 14 threaded down the shaft 30 of a hollow needle 20 having a photodiode 24. A computer 36 evaluates the light a test region and backscattered light detected by photodiode 24 to characterize tissue in the test region by determining oxyhemoglobin and deoxyhemoglobin levels (figs 1-3). Tiemann lacks characterizing the temperature of the sampling site. However, Barker teaches a fluid temperature sensing device 10 for use in a system 11. A thermistor

temperature sensor 14 is disposed in the distal end of the catheter for sensing the temperature of the blood. Computer 16 determines the flow rate of the blood based on the temperature signal from thermistor 14 (fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art to combine the fluid temperature sensing device of Barker with the method and apparatus of Tiemann et al. in order to provide further information to determine a suitable sampling site more accurately.

Claims 62, 80 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Rosenthal. Tiemann discloses collimated light in a range of 340 to 700 nm or 700 nm to 100 nm from an intense light source 10 that is focused on a fiber entrance 16 of an optical fiber 14 threaded down the shaft 30 of a hollow needle 20 having a photodiode 24. A computer 36 evaluates the light a test region and backscattered light detected by photodiode 24 to characterize tissue in the test region by determining oxyhemoglobin and deoxyhemoglobin levels (figs 1-3). Tiemann lacks determining glucose concentration. However, Rosenthal teaches a glucose meter 1 including IRED's 5 and 6 and detector 8 for detecting the light absorbance through a tissue. Processing means 10 determines glucose concentration from absorbance information (fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the glucose meter of Rosenthal with the apparatus and method of Tiemann in order to provide further information enabling a more accurate diagnosis of the patient.

Claims 103-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Rose et al. Tiemann discloses collimated light in a range of

340 to 700 nm or 700 nm to 100 nm from an intense light source 10 that is focused on a fiber entrance 16 of an optical fiber 14 threaded down the shaft 30 of a hollow needle 20 having a photodiode 24. A computer 36 evaluates the light a test region and backscattered light detected by photodiode 24 to characterize tissue in the test region by determining oxyhemoglobin and deoxyhemoglobin levels (figs 1-3). Tiemann lacks instructions for using the device. However, Rose teaches a medical apparatus 10 including an instruction manual 70 (fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include instructions in the apparatus of Tiemann et al. to enable the user to use the apparatus properly, thereby making the apparatus useful.

Claim 106 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Douglas et al. as applied to claims 8-10, 61,63, 79, 81, 99, and 101 above, and further in view of Rose et al. Tiemann, as modified, lacks an instruction manual. However, Rose teaches a medical apparatus 10 including an instruction manual 70 (fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include instructions in the apparatus of Tiemann et al. in view of Osemwota to enable the user to use the apparatus properly, thereby making the apparatus useful.

Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Osemwota as applied to claims 11, 23-26, 31, 60, 64, 70-72, 78, 82, 93-95, 98, and 102 above, and further in view of Rose et al. Tiemann, as modified, lacks instructions for using the device. However, Rose teaches a medical

apparatus 10 including an instruction manual 70 (fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include instructions in the apparatus of Tiemann et al. in view of Osemwota in order to enable the user to use the apparatus properly, thereby making the apparatus useful.

Claim 108 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tiemann et al. in view of Barker as applied to claims 50, 74, and 84 above, and further in view of Rose et al. Tiemann, as modified, lacks instructions for using the device. However, Rose teaches a medical apparatus 10 including an instruction manual 70 (fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include instructions in the apparatus of Tiemann et al. in view of Barker to enable the user to use the apparatus properly, thereby making the apparatus useful.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,452,716 to Clift

U.S. Patent No. 5,551,424 to Morrison

U.S. Patent No. 6,048,312 to Ishrak et al.

U.S. Patent No. 6,167,297 to Benaron

U.S. Patent No. 6,126,600 to Oxaal et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703)

605-0422. The examiner can normally be reached on Mon-Fri 9:30 am-7:00 pm (alternate Fri. off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8117 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

pcm
January 24, 2003

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
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